REMARKS

The claims pending herein are claims 1 and 3-45. Claim 1 has been amended to explicitly state what was already implicit—that the inner material is a core material. Support can be found, for example, throughout out the Summary of the Invention.

Election/Restriction

Applicant was previously required under 35 U.S.C. §121 to choose between the following: (a) Species I, drawn to a medical device with biodegradable inner material and biodegradable outer/covering material and Species II, drawn to a medical device with non-biodegradable inner material and biodegradable outer covering material.

In response, Applicant elected Species I and indicated that claims 1-21 and 45 are readable upon this species.

The examiner argues that claims 3, 4, 9, 10 and 45 do not read upon this species. Applicant respectfully disagrees. Claim 1 is directed to "[a]n implantable or insertable medical device comprising a biodegradable inner material and a biodegradable covering material ..." Claims 3, 4, 9, 10 and 45 depend from claim 1 and therefore contain all the limitations of claim 1, including the limitations directed to "a medical device comprising a biodegradable inner material and a biodegradable covering material." This claim language is essentially identical to the language used in the Office Action mailed March 1, 2005, which set forth Species I as "a medical device with biodegradable inner material and biodegradable outer/covering material."

The examiner argues that hydrogel, metallic and ceramic materials are disclosed in the specification as non-biodegradable materials. However, it does not logically follow that such materials cannot be biodegradable as well.

Indeed, claim 9 as originally filed stated that "the inner material comprises a metallic core," which inner material was further stated in originally filed claim 1 (from which claim 9 depended) to be "a biodegradable inner material."

Similarly, originally filed claim 10 stated that "the inner material comprises a ceramic core," which inner material was unambiguously described in claim 1 (from which claim 10 depended) to be "biodegradable".

With respect to the hydrogel polymers presently pending claim 45, these are all described in paragraph 0048 of the as filed specification as biodegradable core materials.

Accordingly, it is respectfully submitted that claims 1-21 and 45 are readable upon species I as previously asserted.

Claim Rejection under 35 U.S.C. §112, First Paragraph

Claims 1-19 and 45 are rejected under 35 U.S.C. §112, first paragraph as allegedly not reasonably providing enablement for a biodegradable inner material being metallic or ceramic. This rejection is respectfully traversed.

Turning to MPEP 2164.01, a pertinent portion thereof reads as follows:

> Any analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention. The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916) which postured the question: is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).... See also *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988) ("The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.")....

With respect to the biodegradable metallic inner core material of claim 9, it should be noted that a variety of biodegradable metallic materials were known at the time of filing of the present application, including magnesium, iron, and alloys of magnesium and iron, among others. See, e.g., U.S. Patent Appln. Pub. No. 2002/0004060 entitled "Metallic Implant which is Degradable In Vivo." See, also, e.g., U.S. Patent Appln. Pub. No. 2001/0044651 entitled "Expandable Stent with Sliding and Locking Radial Elements," which describes magnesium alloys as preferred degradable materials in paragraph 0093, and M. Peuster et al., "A novel approach to temporary stenting: degradable cardiovascular stents produced from corrodible metal-results 6-18 months after implantation into New Zealand white rabbits," *Heart*, 2001 Nov; 86(5):563-9 (Abstract attached), which describes corrodible iron stents.

Similarly with respect to the biodegradable ceramic inner core material of claim 10, a variety of biodegradable ceramic materials were also known at the time of filing of the present

application, including Hydroxyapatite (HA), aluminum-calcium-phosphorous oxide (ALCAP), and tricalcium phosphate (TCP), among others. See, e.g., H. A. Benghuzzi et al, "Controlled release of hydrophilic compounds by resorbable and biodegradable ceramic drug delivery devices," *Biomed Sci Instrum*, 1992; 28:179-82 (Abstract attached). See also, U.S. Patent Appln. Pub. No. 2001/0044651 entitled "Expandable Stent with Sliding and Locking Radial Elements," which describes calcium phosphate as a preferred degradable material in paragraph 0093.

In view of the disclosures in the present patent application, coupled with information known in the art concerning biodegradable metallic and ceramic materials, it is respectfully submitted that one reasonably skilled in the art would have been able to make and use the claimed invention without undue experimentation. See, e.g., *United States v. Telectronics, Inc* in the above excerpt from MPEP 2164.01.

Reconsideration and withdrawal of the rejection of claims 1-19 and 45 under 35 U.S.C. §112, first paragraph, are therefore requested.

Claim Rejection under 35 U.S.C. §102—Datta et al.

Claims 1, 5-8, 11-21 are rejected under 35 U.S.C. §102(e) as being anticipated by Datta et al., U.S. 6,338,739. Applicant respectfully traverses this rejection and its supporting remarks.

For example, independent claim 1 is presently directed to an implantable or insertable medical device comprising a biodegradable inner core material and a biodegradable covering material at least partially covering the inner core material, which, after insertion or implantation into a patient, becomes decreasingly rigid and increasingly biomechanically compatible with body tissue in contact with the device over time. The biodegradable inner core material is selected from (a) a hydrogel material that becomes flexible upon contact with body fluids, (b) a metallic material, and (c) a ceramic material.

With respect to element (a) of claim 1, Datta et al. does not appear to teach or suggest an inner core hydrogel material that becomes flexible upon contact with body fluids.

With respect to claim elements (b) and (c), Datta et al. does not appear to teach or suggest biodegradable ceramic or metallic materials, but rather is directed to biodegradable polymers.

For at least these reasons, it is respectfully submitted that claim 1 is patentable over Datta et al. Claims 3-21 and 45 depend from claim 1 and are therefore patentable over Datta et al. for at least the same reasons as is claim 1.

Reconsideration and withdrawal of the rejection of these claims as anticipated by Datta et al. are requested.

Claim Rejection under 35 U.S.C. §102—Wang et al.

Claims 1, 5-8, 11-21 are rejected under 35 U.S.C. §102(a) as being anticipated by Wang et al., WO 98/56312. Applicant respectfully traverses this rejection and its supporting remarks.

For example, independent claim 1 is directed to an implantable or insertable medical device comprising a biodegradable inner core material and a biodegradable covering material at least partially covering the inner core material, which, after insertion or implantation into a patient, becomes decreasingly rigid and increasingly biomechanically compatible with body tissue in contact with the device over time. The biodegradable inner core material is selected from (a) a hydrogel material that becomes flexible upon contact with body fluids, (b) a metallic material, and (c) a ceramic material.

With respect to claim elements (b) and (c) of claim 1, Wang et al. does not appear to teach biodegradable ceramic or metallic materials, but rather is directed to biodegradable polymers.

With respect to claim element (a), Wang et al. teaches that the outer layer may be used as a drug-delivery system to prevent restenosis or for other treatment. *Id.* at page 7, lines 5-6. For carrying drugs, a gel-like material may be used. *Id.* at line 18. Due to their gel-like nature, a stent can then be inserted into a drug solution, and the drug will be absorbed into/onto the gel. *Id.* at lines 24-25. The stent can then be delivered into the body (dried or not dried). *Id.* at line 26. The drug will be released. *Id.* at lines 26-27.

Wang et al., however, does not appear to teach the use of a gel-like material as an inner core material as presently claimed in claim 1.

For at least these reasons, it is respectfully submitted that claim 1 is patentable over Wang et al. Claims 3-21 and 45 depend from claim 1 and are therefore patentable over Wang et al. for at least the same reasons as is claim 1.

Reconsideration and withdrawal of the rejection of these claims as anticipated by Wang et al. are requested.

CONCLUSION

Applicant submits all pending claims are in condition for allowance, early notification of which is earnestly solicited. Should the Examiner be of the view that an interview would expedite consideration of this Amendment or of the application at large, request is made that the Examiner telephone the Applicant's attorney at (703) 433-0510 in order that any outstanding issues be resolved.

FEES

If there are any fees due and owing in respect to this amendment, the Examiner is authorized to charge such fees to deposit account number 50-1047.

Respectfully submitted,

Attorney for Applicant
Mayer Fortkort & Williams PC
251 North Avenue West, 2nd Floor
Westfield, NJ 07090

Tel.: 703-433-0510

David B. Bonham
Registration No. 34,297

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I hereby certify that this document and any document referenced herein is being sent to the United States Patent and Trademark office via Facsimile to: 571-273-8300 on Sept. 28, 2005

David B. Bonham
(Printed Name of Person Mailing Correspondence)

(Signature)

1: Heart. 2001 Nov;86(5):563-9.

Related Articles, Links

A novel approach to temporary stenting: degradable cardiovascular stents produced from corrodible metal-results 6-18 months after implantation into New Zealand white rabbits.

Peuster M, Wohlsein P, Brugmann M, Ehlerding M, Seidler K, Fink C, Brauer H, Fischer A, Hausdorf G.

Department of Paediatric Cardiology and Paediatric Intensive Care, Children's Hospital, Georg-August University, Robert-Koch-Str 40, D-37085 Goettingen, Germany. matthias.peuster@medizin.uni-goettingen.de

OBJECTIVE: To determine whether corrodible materials may be safely used as biodegradable cardiovascular implants. DESIGN: Corrodible iron stents (> 99.8% iron) were produced from pure iron and laser cut with a stent design similar to a commercially available permanent stent (PUVA-AS16). A total of 16 NOR-I stents were implanted into the native descending aorta of 16 New Zealand white rabbits (mean luminal diameter at the implantation site 3.4 mm, balloon diameter to vessel diameter ratio 1.13). RESULTS: No thromboembolic complications and no adverse events occurred during the follow up of 6-18 months. All stents were patent at repeat angiography after 6 (n = 9), 12 (n = 5), and 18 months (n = 2) with no significant neointimal proliferation, no pronounced inflammatory response, and no systemic toxicity. CONCLUSIONS: This initial in vivo experience suggests that degradable iron stents can be safely implanted without significant obstruction of the stented vessel caused by inflammation, neointimal proliferation, or thrombotic events.

PMID: 11602554 [PubMed - indexed for MEDLINE]

Biomed Sci Instrum. 1992;28:179-82. Related Articles, Links

Controlled release of hydrophilic compounds by resorbable and biodegradable ceramic drug delivery devices.

Benghuzzi HA, England BG, Bajpai PK.

Pathology Department University of Michigan, Ann Arbor 48109.

Hydroxyapatite (HA), aluminum-calcium-phosphorous oxide (ALCAP), bone meal (BM), and tricalcium phosphate (TCP) ceramic implants are biodegradable and nontoxic to the host. The purpose of this study was to investigate the capability of these ceramics to deliver the catecholamine, epinephrine (EPI) in a sustained and controlled manner. The ceramic powder (less than 38 um particle size) was prepared in our laboratory using standard procedures. Sixteen cylinders were prepared (1 g each) from each of the four ceramic materials. All cylinders were pressed at a compression load of 615 Kg and sintered for 36 hours. ALCAP (group I) and BM (group II) cylinders were sintered at 1400 degrees C and HA (group III) and TCP (group IV) ceramic capsules were sintered at 1150 degrees C. Three capsules from each group were loaded with 30 mg EPI. Capsules containing EPI and control (empty) capsules were each suspended in a serum bottle containing 100 ml of phosphate buffered saline (pH 7.4). The amount of EPI released from each capsule was determined by spectrophotometric methods. Data collected from this study showed that the rate of release of EPI from ALCAP, HA, BM and TCP was 6.14 +/- 0.3 3.55 +/- 0.29, 2.07 +/- 0.26 and 1.17 +/- 0.04 mg/day, respectively.(ABSTRACT TRUNCATED AT 250 WORDS)

PMID: 1322731 [PubMed - indexed for MEDLINE]